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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,636	08/03/2001	Manfred Mutter	2548-17	5241

7590

05/30/2002

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/890,636

Applicant(s)

Mutter

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 25, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

Applicants' election of Group II (claims 1-4, drawn to compounds, limited to G2) without traverse is acknowledge, as is the elected specie (the compound of example 3 in which R1 is phenyl and R2 is hydrogen).

\*

Applicants are reminded of the preferred arrangement of the specification:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The following section heading is required:

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

The following section heading is recommended:

DETAILED DESCRIPTION OF THE INVENTION

In addition, the "BRIEF DESCRIPTION OF THE DRAWINGS" should precede the "DETAILED DESCRIPTION OF THE INVENTION" section. What is suggested is that the description of the figures which is now present on page 4, lines 21+ be moved to an earlier location, such as

page 2, line 6.

\*

Claims 1-4 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites the following:

“a residue of a water-soluble polymer, possibly bound to a spacer group”.

First, since this is the last member of the Markush Group, this phrase should be preceded by the conjunction “or”, or else the conventional “selected from the group consisting of” language should be adopted. Second, the term “bound” could encompass both covalent and non-covalent bonding; if covalent bonding only is intended, then the term *bonded* would be better. In addition, the term *optionally* is preferable to “possibly”. Following is one option for claim language:

*...or R<sup>1</sup> and R<sup>2</sup> each independently denotes a water soluble polymer, wherein said polymer is optionally bonded to the carbon bearing R<sup>1</sup> and R<sup>2</sup> via a spacer group.*

Another option would be to create two new substituent variables (e.g., “X” and “L”) and to adopt the following language:

*...or R<sup>1</sup> and R<sup>2</sup> each independently denotes a group X-L-, wherein X is a water soluble polymer, and L is a covalent bond or a spacer moiety.*

- Each of claims 1 and 2 recite the phrase “general formula I”. Here, the term “general” is superfluous and can be eliminated.
- In the claims, the term *wherein* is preferable to “characterized in that”.
- Each of claims 3, 4 and 6 recite the term “sistine”. The spelling *cysteine* should be

used, if that is what is intended.

- Claims 3 and 6 recite the phrase: "d or l configuration". Here, the "d" and "l" should be uppercase (**D** and **L**), since amino acids are at issue.
- In claim 4, the phrase "the basic cyclosporin" lacks antecedent basis.

\*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6 are rejected under 35 U.S.C. §102(b) as being anticipated by Wohr (*J. Am. Chem. Soc.* **118**, 9218, 1996).

Wohr discloses (Scheme I, page 9219) a compound designated Xaa( $\Psi^{R',R''}$  pro), and its incorporation into various peptides. The cited claims are anticipated, since there are no limits on what the term cyclosporin "derivative" might encompass. The term "derivative" could include any number of amino acid substitutions, such that the core structure of cyclosporin is no longer recognizable as such.

\*

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The Chem Abstracts citation was stricken from the IDS, since a copy was not received.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800